Remarks

In view of the foregoing amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

This amendment is being filed along with a Request for Continued Examination ("RCE") and a petition for a five-month extension of time from the July 17, 2007 due date for filing of an appeal brief. No appeal brief has been filed. Therefore, the RCE and this amendment are timely filed.

New claim 49 has been introduced, claims 2-5, 24, 44, 45, and 48 have been cancelled, and claims 6, 7, 9-13, 15-17, 25-39, 42, 46, and 47 have been amended. Claims 6, 7, 9-13, 15-17, 25-39, 42, 46, 47, and 49 remain pending.

New claim 49 finds descriptive support at page 4, line 29 to page 5, line 5, and page 7, lines 14-17 (describing formation of the polymeric antimicrobial from poly(2-propenal, 2-propenoic acid); page 5, line 5 to page 7, line 12 (describing formation of poly(2-propenal, 2-propenoic acid) reactant from homopolymer of acrolein by ionic polymerization and auto-oxidation); page 7, lines 14-23, page 8, lines 4-9, page 8, line 32 to page 9, line 2, and page 20, line 2, to page 21, line 8 (comparison of poly(2-propenal, 2-propenoic acid) reactant with polymeric antimicrobial product obtained following "super-activation" by heating in the presence of polyol); and page 4, lines 20-23 and lines 25-26, page 8, line 32 to page 11, line 16 (treatment or prophylaxis of gastrointestinal disease in an animal using polymeric antimicrobial). Further descriptive support for the fixing of poly(2-propenal, 2-propenoic acid) from a homopolymer of acrolein by ionic derivation and oxidation is provided in PCT Publ. No. WO 96/38186 to Melrose ("Melrose I"), which is incorporated by reference into the contents of the present application at page 5, lines 6-7. From the foregoing, no new matter is introduced by claim 49.

The rejection of claims 2-7, 9-13, 15-17, 24-39, 42, and 44-48 under 35 U.S.C. §§ 102(b), 103(a) as anticipated by or for obviousness over Melrose I is respectfully traversed.

As mentioned briefly above, Melrose I teaches the formation of poly(2-propenal, 2-propenoic acid) from acrolein homopolymers and its use to treat or prevent gastrointestinal disease in various animals. Thus, Melrose I merely describes how to form the starting material that can be used to form the polymeric antimicrobial which is administered in accordance with claim 49.

While Melrose I discloses the poly(2-propenal, 2-propenoic acid) from which the recited polymeric antimicrobial may be formed, Melrose I does not disclose formation of the recited polymeric antimicrobial antimicrobial product. As noted above, Melrose I describes forming the starting material, poly(2-propenal, 2-propenoic acid), which is fixed from a homopolymer of acrolein by ionic derivation and oxidation. However, Melrose I fails to teach or suggest further treating the product poly(2-propenal, 2-propenoic acid) by "heating poly(2-propenal, 2-propenoic acid) in a polyol at a temperature in the range from 40°C to 150°C for a time sufficient to increase the antimicrobial activity of the poly(2-propenal, 2-propenoic acid)."

As discussed in detail below and in applicants' previously submitted response (dated April 13, 2007), the manner by which the present invention was made and the examples of the present application—showing unexpected properties—clearly demonstrate that the polymeric antimicrobial prepared under these conditions is neither taught nor suggested by Melrose I, nor would it have been inherently produced in any of the Examples reported in Melrose I.

The present application explains that formation of the recited polymeric antimicrobial, by heating poly(2-propenal, 2-propenoic acid) in the presence of a polyol at a temperature in the range from 40°C to 150°C for a sufficient duration, uses conditions normally associated with accelerated aging studies. Page 20 of the application recites:

> The invention has been found to significantly increase the stability of poly(2-propenal, 2-propenoic acid) polymers. Since the prior art recorded some instability of poly(2-propenal, 2-propenoic acid), as evidenced by loss of antimicrobial activity of its compositions, we conducted "accelerated ageing" at elevated temperature, ie. at 40°C. However, to our greatest surprise, the elevated temperature of "ageing" poly(2-propenal, 2-propenoic acid) in aqueous or in aqueous-polyethylene glycol solutions at 40°C, not only slowed the decrease in antimicrobial activity-but in fact, actually increased antimicrobial activity of the poly(2-propenal, 2-propenoic acid), see Example 2(a) and (b). This finding is totally contradictory and unexpected in view of the prior art which predicts that the rise in temperature should lead to "accelerated ageing", ie. accelerated loss of antimicrobial activity.

Page 20,lines 2-13.

Examples 10 and 11 of the present application describe the preparation and compare the efficacy of the starting material poly(2-propenal, 2-propenoic acid) and the derivative polymeric antimicrobial. In Example 10a, poly(2-propenal, 2-propenoic acid) is prepared in accordance with the general procedure of Example 1b of Melrose I. In part 2 of Example 10(a), polyacrolein is prepared using an ionic catalyst (sodium hydroxide) in water.

In part 4 of this same example, the polyacrolein is dried and oxidized in air to provide poly(2-propenal, 2-propenoic acid). Example 10(b) describes forming the polymeric antimicrobial by heating poly(2-propenal, 2-propenoic acid) and polyethylene glycol at 100°C for 4 hours. Example 11 demonstrates that the derivative polymeric antimicrobial (prepared in Example 10b) has a statistically significant improvement in activity against gastrointestinal disease when compared with poly(2-propenal, 2-propenoic acid) of Melrose I (prepared in Example 10a).

Thus, from the description in the present application and the comparative examples, the poly(2-propenal, 2-propenoic acid) of Melrose I and the recited polymeric antimicrobial—prepared in the manner recited in claim 49—are structurally distinct and possess different activity. For the reasons asserted in applicants' request for reconsideration filed on April 13, 2007, none of the portions of Melrose I that are cited by the PTO for inherency (i.e., cited on pages 6 through 8 of the outstanding office action) recite the types of process conditions presented in claim 49. Therefore, it is improper for the PTO to assert that Melrose I would have inherently obtained the recited polymeric antimicrobial using the distinct processes of Melrose I.

Despite applicants' prior explanation as to why this is so, the PTO continues to assert in the Advisory Action that Melrose I "illustrates a reaction of the subject polymers poly(2-propenal, 2-propenoic acid) with polyethylene glycol at room temperature up to 100°C to increase hydrophilicity and utility in the application of treating diseases of the gastrointestinal tract of humans, animals and birds." In making this assertion, the PTO cites to page 3, lines 25-35, page 7, lines 5-15, and Examples 1, 13, and 15 of Melrose I. None of these cited portions of Melrose I involve "heating poly(2-propenal, 2-propenoic acid) in a polyol at a temperature in the range from 40°C to 150°C for a time sufficient to increase the antimicrobial activity of the poly(2-propenal, 2-propenoic acid)." Therefore, the conclusion of the PTO is without basis.

Even if *prima facie* obviousness could be sustained (which applicants submit is improper for the reasons noted above), then the showing of significant advantages in efficacy of the recited polymeric antimicrobial derivatives over the poly(2-propenal, 2-propenoic acid) starting material demonstrates that the invention cannot be regarded as obvious.

For all these reasons, the rejection of claims 2-7, 9-13, 15-17, 24-39, 42, and 44-48 as anticipated by or for obviousness over Melrose I is improper and should be withdrawn.

The rejection of claims 2-7, 10, 13, 16, 17, 24-25, 28, 30, 31, 42, and 46-48 for obviousness-type double patenting over claims 1, 10, 18, 22, 24, and 28 of U.S. Patent No. 6,410,040 to Melrose et al. ("Melrose II") is respectfully traversed.

The claims of Melrose II cited by the PTO relate to methods of preparing compositions of poly(2-propenal, 2-propenoic acid). The specification of Melrose II makes clear that the recited method steps are intended to result in a stable solution of poly(2-propenal, 2-propenoic acid) that resists precipitation. Importantly, the claims of Melrose II encompass different statutory classes of subject matter from that which is presently claimed (i.e., methods of use) and Melrose II fails to recite any polymeric antimicrobial that is prepared according to the process recited in claim 49. Absent such showing, the presently claimed methods of use cannot have been obvious over the claims of Melrose II.

Because the rejection is improper for the reasons noted above, the obviousness-type double patenting rejection over claims of Melrose II is improper and should be withdrawn.

The rejection of claim 2-7, 9-13, 15-17, 24-39, 42, and 44-48 for obviousness-type double patenting over claims 1-36 of U.S. Patent No. 6,723,336 to Melrose ("Melrose III") is respectfully traversed.

Melrose III is related to Melrose I as the corresponding U.S. national phase. Thus, the disclosure of these references is identical. For the same reasons discussed above with respect to Melrose I, Melrose III fails to teach treating the product poly(2-propenal, 2-propenoic acid) by "heating poly(2-propenal, 2-propenoic acid) in a polyol at a temperature in the range from 40°C to 150°C for a time sufficient to increase the antimicrobial activity of the poly(2-propenal, 2-propenoic acid)."

While the cited claims of Melrose III relate to methods for treatment of poultry or piglets by administration of the poly(2-propenal, 2-propenoic acid) polymers recited therein, for substantially the same reasons noted above the presently claimed methods encompass use of a different product that is produced under the recited conditions and has improved activity as compared to the poly(2-propenal, 2-propenoic acid) material from which it is derived. Melrose III in no way teaches or suggests the formation of the recited polymeric antimicrobial, let alone use thereof. Thus, the cited claims of Melrose III would not have rendered obvious the presently claimed methods of use.

Because the rejection is improper for the reasons noted above, the obviousness-type double patenting rejection over claims of Melrose III should be withdrawn.

In view of all of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: December 17, 2007

/Edwin V. Merkel/
Edwin V. Merkel
Registration No. 40,087

NIXON PEABODY LLP
1100 Clinton Square
Rochester, New York 14604
Telephone: (585) 263-1128
Facsimile: (585) 263-1600